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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,211

10/30/2006

Bakulesh Mafatlal Khamar

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25227 7590 04/08/2008  
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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

04/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,211	<b>Applicant(s)</b> KHAMAR, BAKULESH MAFATLAL	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 22-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2008 has been entered.
2. Claims 22-48 are pending and under consideration.

### **Rejection Maintained**

3. The rejection of claims 22-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is maintained.

Applicant argues that the specification provides clear and sufficient guidance to one of ordinary skill in the art on how to make and/or use the claimed invention. Specifically, the present application includes numerous references to human hosts. (See e.g., Examples 4-8). Indeed, all of the examples are illustrated with human patients. Further, regarding the dosage and composition, Example 1 provides 10 different recipes. Example 6 teaches giving patients 0.1 ml doses at a rate of 1 per week. Additionally, Example 2 teaches the preparation of a pharmaceutical composition in great detail. Regarding frequency and duration, example 4 teaches treating the patient once a week while example 7 teaches treating patients according to a conventional regimen for three months. Regarding the route of administration, the specification teaches that asthma medications may be inhaled or taken orally with the preferred method being inhalation. (See pages 2-3 of the instant application). One of ordinary skill in the art reading the specification would clearly understand that typical treatment conditions would

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comprise giving a patient approximately 0.1 ml doses once a week for four weeks to three months.

In addition, Dr. Khamar, one of the inventors on this application, submits herewith a declaration under 37 C.F.R. § 1.132 providing additional experimental data supporting the compositions, dosages, and treatment regimens taught in the specification. The additional experimental data in the Rule 132 declaration of Dr. Khamar simply provide further clarifications of the examples that were reduced to practice by the inventors. However, as explained in paragraph 9 of the Rule 132 of Dr. Michael Ross, MD, the additional data in the Rule 132 declaration of Dr. Khamar are nothing more than "minor details." However, "the omission of minor details does not cause a specification to fail to meet the enablement requirement" as the "minor details" supplement, not substitute the specification. See Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361 (Fed. Cir. 1997). In short, Applicants submit that one of ordinary skill in the art reading the specification would have sufficient guidance to prepare a pharmaceutically effective composition, dosage and treatment regimen as claimed and respectfully request withdrawal of the rejection.

The Declaration of Dr. Khamar recites that in the examples 5 to 7, "a pharmaceutical composition of Mycobacterium w" was administered intradermally or by nebulizer in quantities of 0.2 ml or 0.1 ml once a week or once a fortnight.

The examiner has considered applicant's arguments, but does not find them persuasive. The instant specification does recite 8 different preparations of Mycobacterium w pharmaceutical composition, i.e., heat killed whole cells, methanol extract, chloroform extract, sonicate, acetone extract, ethanol extract, and lipoase extract. However, neither the specification nor the Declaration of Dr. Khamar specifies which of the types was actually

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utilized. Because of the wide variety of the composition preparations, the actual constituents in each of the pharmaceutical compositions also vary greatly. Thus, without knowing exactly which preparation was utilized, there is insufficient information to enable the instant claims which merely recite "a pharmaceutical composition comprising an effective amount of" either "Mycobacterium w" or "a" constituent of Mycobacterium w.

### **Conclusion**

4. No claims are allowed.
5. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 30, 2008 April 7, 2008

<b>Application Number</b> 	<b>Application/Control No.</b> 10/565,211	<b>Applicant(s)/Patent under Reexamination</b> KHAMAR, BAKULESH MAFATLAL	
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645	